

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TWINSTRAND BIOSCIENCES, INC., &
UNIVERSITY OF WASHINGTON,

Plaintiffs,

v.

GUARDANT HEALTH, INC.,

Defendant.

C.A. No. 21-1126-LPS

JURY TRIAL DEMANDED

**DEFENDANT GUARDANT HEALTH, INC.'S OPPOSITION TO PLAINTIFFS'
OPENING BRIEF IN SUPPORT OF THEIR PARTIAL MOTION TO DISMISS
GUARDANT HEALTH'S COUNTERCLAIMS (COUNTS V–VIII) AND RELATED
AFFIRMATIVE DEFENSES**

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I. INTRODUCTION

TwinStrand Biosciences, Inc.’s, (“TwinStrand”) and University of Washington’s (“UW,” collectively, “Plaintiffs”) partial motion to dismiss Defendant Guardant Health, Inc.’s (“Guardant”) Counterclaim Counts V–VIII and to strike Guardant’s Fourth, Eighth, and Twelfth affirmative defenses should be denied on all grounds. First, Guardant’s inequitable conduct allegations meet the heightened pleading standard because Guardant specified the material omission—that the inventors did not disclose that they copied claims from Guardant patents—and pled facts establishing the who, what, when, where, and how of the inventors’ inequitable conduct. Second, Guardant’s unpatentability counterclaims and affirmative defenses are adequately pled because: (1) they plausibly allege that the asserted patents fail to identify the true inventors of the claimed inventions, *i.e.*, the inventors from whom TwinStrand copied its asserted claims; (2) pre-AIA § 135 provides a cause of action (and, even if it does not, it does not support dismissing the counterclaims in their entirety); and (3) Guardant’s affirmative defenses provide fair notice and thus are adequately pled under Fed. R. Civ. P. 12(f).

II. BACKGROUND

Plaintiffs filed suit against Guardant on August 3, 2021 alleging infringement of four patents owned by UW and exclusively licensed to TwinStrand. D.I. 1. Guardant denied these allegations in its October 1, 2021 answer. D.I. 10. Guardant filed an amended answer and counterclaims on January 12, 2022, (1) asserting four Guardant patents against TwinStrand (Counts I–IV), (2) asserting two counts of unpatentability under 35 U.S.C. §§ 101, 115, and/or 135 (Counts V, VI), and (3) asserting two counts of inequitable conduct (Counts VII, VIII). D.I. 30. Guardant also asserted several affirmative defenses, including a defense based on improper inventorship and derivation (Fourth Affirmative Defense), Plaintiffs’ and other’s unclean hands

during prosecution of TwinStrand's patents (Eighth Affirmative Defense), and failure to comply with the conditions of patentability under § 135 (Twelfth Affirmative Defense).

Guardant's inequitable conduct, unpatentability, and improper inventorship counts and defenses describe TwinStrand's pattern of claim copying—misappropriating the inventions of its competitors' patents. D.I. 30 at ¶¶ 124-125, 140-148, 265, 290. Indeed, in U.S. Patent Application No. 16/411,066, TwinStrand wholesale withdrew all pending claims during prosecution, and then added new claims 37-66 that very closely track Guardant's issued patent's claims. TwinStrand did this knowing it had no support in its initial application for these claims (*see* D.I. 30 at p. 19 (Third Affirmative Defense)) and without notifying the Examiner of its claim copying. Indeed, TwinStrand completely disregarded § 135(b) and ignored the procedures in place to provoke an interference.

With its ill-gotten claims, TwinStrand filed its Complaint in the instant case, asserting that Guardant's products practice those same claims. Guardant responded with counterclaims and affirmative defenses based on TwinStrand's improper actions. And despite that every one of Guardant's counts and affirmative defenses is supported by factual allegations commensurate with its respective pleading requirements, TwinStrand asks this Court to deny Guardant the opportunity to defend the claims on these bases.

III. LEGAL STANDARD

A court conducts a two-part analysis when presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). The court first separates the factual and legal elements of a claim, accepting all the complaint's well-pleaded facts as true while disregarding any legal conclusions. *Id.* at 210-11. The court then determines whether the factual allegations in the complaint, or as in the instant

case, counterclaims, are sufficient to show that the counterclaim-plaintiff has a “‘plausible claim for relief.’” *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. The court must “‘accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.’” *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). A plaintiff “‘need not ‘prove its case at the pleading stage’” or “‘plead facts establishing that each element of an asserted claim is met.’” *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1350 (Fed. Cir. 2018).

“When ruling on a motion to strike, ‘the [c]ourt must construe all facts in favor of the nonmoving party and deny the motion if the defense is sufficient under law.’” *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 356 (D. Del. 2009) (citations omitted). “Due to the ‘differences between Rules 8(a) and 8(c) in text and purpose, [] *Twombly* and *Iqbal* do not apply to affirmative defenses,’ which ‘need not be plausible to survive. [An affirmative defense] must merely provide fair notice of the issue involved.’” *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 303–04 (D. Del. 2013) (quoting *Internet Media Corp. v. Hearst Newspapers, LLC*, No. 10-690-SLR, 2012 WL 3867165, at *3 (D. Del. Sept. 6, 2012)).

IV. ARGUMENT

All of Guardant’s counterclaims and affirmative defenses are adequately pled. Guardant’s allegations of inequitable conduct in Counts VII and VIII meet the heightened pleading requirements of Rule 9(b) because they sufficiently identify the who, what, when, where, and how of the inventors’ material omission before the Patent and Trademark Office.

Guardant sufficiently pled each substantive element where it included facts identifying (1) the specific individuals involved in prosecution; (2) the specific claims that are copies of other claims; and (3) explained why the withheld disclosure of claim copying establishes unpatentability. At this pleading stage, Guardant is not required to prove its entire case.

Guardant's allegations of unpatentability in Counts V and VI are also sufficient. Guardant has alleged facts that demonstrate Plaintiffs did not meet the requirements of Sections 101, 115, and 135 for failure to properly identify the true inventors. Plaintiffs' motion, though, only disputes the applicability of Section 135, thus conceding these counts survive under §§ 101 and 115. On that basis alone, Plaintiffs' motion as to these counts should be denied. But Section 135 can properly be raised as an invalidity defense in a district court litigation, and Plaintiffs cite no controlling authority to the contrary.

Guardant's affirmative defenses are likewise sufficient to put Plaintiffs on notice and should not be stricken.

A. Guardant Pled Sufficient Facts To Support Its Inequitable Conduct Counterclaims.

1. Guardant Pled Specific Facts Alleging Plaintiffs' Failure To Notify The PTO Of Plaintiffs' Claim Copying.

Guardant's allegations of inequitable conduct in Counts VII and VIII meet the heightened pleading requirements of Rule 9(b) because they sufficiently identify the who, what, when, where, and how of the material omission before the Patent and Trademark Office ("PTO"). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009) (to plead inequitable conduct, "the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO"). The parties agree "[t]he substantive elements of inequitable conduct are: (1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material

fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the PTO.” D.I. 39 at 6, citing *Exergen*, 575 F.3d at 1327, n.3; *see also Sanders v. The Mosaic Co.*, 418 F. App'x 914, 919 (Fed. Cir. 2011) (“At the pleading stage the proponent of the inequitable conduct theory need only plead facts supporting a reasonable inference that a specific individual knew of the misrepresentation and had the specific intent to deceive the PTO.”).

Guardant properly alleged why the withheld disclosure of claim copying establishes unpatentability and adequately pled each substantive element, satisfying the *Exergen* standard by specifying the who, what, when, where, and how of the alleged inequitable conduct.

Who: Guardant specifically identified “Jesse Salk, Lawrence Loeb, Michael Schmitt, and Lara J. Dueppen” as individuals involved in the prosecution of the applications that issued as the ’699 and ’951 patents. D.I. 30 at ¶¶ 248, 252-253, 257, 260-261, 263-267, 269, 271, 278, 282, 285-292, 294. Therefore, Guardant satisfies the “who” requirement.

What and where: Guardant also identified the claims of the ’699 and ’951 patents that it alleges were copied, pleading “claims 37-39 and 41-43 of the ’066 Application were copied from the ’822 Patent” (D.I. 30 at ¶ 257) and “claims 1-2 of the ’931 Application were copied from the ’427 Application” (*Id.* at ¶ 282). Therefore, Guardant satisfies the “what” and “where” requirements.

Why and how: Guardant identified both why the intentional failure to disclose the copied claims was material and how the withheld information would have been used to preclude the issuance of the ’699 and ’951 patents. Guardant’s allegations include that the failure to notify the PTO “constitutes disreputable or gross misconduct” with specific citations to statutes and the Manual of Patent Examining and Procedure (D.I. 30 at ¶¶ 257, 283). Guardant also alleges that

“identifying the copied claims would have triggered an interference, a much more thorough and in-depth examination as to whether the claims of the [] Application were entitled to be issued in light of the existence of identical claims in a previously-issued U.S. Patent.” (D.I. 30 at ¶¶ 262, 287). Therefore, Guardant satisfies the “why” and “how” requirements.

Plaintiffs’ reliance on *Exergen* is misplaced. In *Exergen*, the Court found three deficiencies in the allegations: (1) the “who” requirement was not met where the pleading failed “to name the specific individual associated with the filing or prosecution of the application”; (2) the “what” and “where” requirements were not met where the pleading failed “to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found”; and (3) the “why” and “how” requirements were not met where the pleading did “not identify the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record.” 575 F.3d at 1329. None of those deficiencies are present in Guardant’s counts. As shown above, Guardant sufficiently pleaded the specific individuals, the relevant claims, and the material omission. Indeed, Plaintiffs concede that Guardant pled “a single alleged omission in each inequitable-conduct count,” D.I. 39 at 8, which is dispositive since Guardant also alleges that omission was intentional and material.

2. Guardant Pled Intent To Deceive Where Clear Claim Copying Was Not Disclosed To The PTO.

Guardant has pled, with sufficient detail, that Jesse Salk, Lawrence Loeb, Michael Schmitt, and Lara J. Dueppen engaged in a “practice of copying claims into their own applications without disclosing that the claims are copied.” (D.I. 30 at ¶¶ 265, 290). Guardant also identified five other instances of undisclosed claim copying, and that in the one instance where claim copying was disclosed, “no patent issued.” *Id.* at ¶¶ 268, 293. And Plaintiffs

concede that Guardant alleged “the relevant people were experienced with prosecution and knew they had a duty to disclose claim copying to the Patent Office.” D.I. 39 at 9. “[S]uch intent to mislead the PTO is the only reasonable inference from the totality of the circumstances alleged in this counterclaim.” D.I. 30 at ¶¶ 264, 289.

Plaintiffs suggest that Guardant must prove at the pleading stage that specific intent is the only reasonable inference based on the allegations. *See* D.I. 39 at 10 (stating that a “strong inference of fraudulent intent” is required (citing *Exergen*, 575 F.3d at 1327, n.4)). But this level of proof is not required at the pleading stage. “Defendants are not required at the pleading stage to prove (or even plead) that a specific deceptive intent is the single most reasonable inference to be drawn from the facts alleged.” *Diebold Nixdorf, Inc. v. Hyosung Tns, Inc.*, No. 19-1695-LPS, 2021 WL 861734, at *4 (D. Del. Mar. 4, 2021).

But even under Plaintiffs’ proposed heightened standard, Guardant’s allegations pass muster. Experienced inventors and prosecuting counsel engaged in a pattern of copying claims and withheld the fact of that copying from the PTO and this establishes a strong inference of fraudulent intent. That the inventors “cited the ’822 patent to the Patent Office in an IDS,” D.I. 39 at 11, bolsters the inference because it establishes they knew of the ’822 patent’s claims and *affirmatively failed to disclose* they copied those claims. Further, that the inventors “on one occasion copied claims in the ’305 application and notified the Patent Office,” *Id.* at 13, supports that the inventors engaged in a systemic practice of copying claims, and reinforces that the inventors and counsel knew of their obligation to inform the PTO. Thus, Guardant’s allegations support the strong inference “that a specific individual was not just aware of the Guardant application but also knew of the specific claims and that they were substantially copied.” *Id.* at 12. Plaintiffs ask the Court to ignore the strong inference of fraudulent intent based on the

alleged facts and weigh other possible inferences, but “[w]hether Defendants will ultimately prove that a specific intent to deceive is the single most reasonable inference is a matter for another day.” *Diebold Nixdorf*, 2021 WL 861734, at *4.

Plaintiffs’ remaining arguments go to the weight of Guardant’s arguments, and not the sufficiency of its allegations, and thus, do not support dismissal. *Quest Integrity USA, LLC v. Clean Harbors Indus. Servs., Inc.*, No. 14-1482-SLR, 2015 WL 4477700, at *1 n.4 (D. Del. July 22, 2015) (“The court does not rely on the parties’ substantive arguments to determine whether the inequitable conduct allegations were sufficiently pled.”). The veracity of an allegation is improperly addressed in a motion to dismiss. *York Bldg. Prod. Co. v. Mumma*, No. 10-1677-JEJ, 2011 WL 13214367, at *3 (M.D. Pa. Aug. 9, 2011) (refusing to consider certain evidence on a motion to dismiss because such consideration “would require a determination of its reliability and weight, which would be inappropriate for the Court to conduct at this time.”).

For example, Plaintiffs argue that “Guardant’s allegation in Count VII (which it omits from Count VIII) that Plaintiffs filed exact copies of Guardant’s ’822 patent should be given no weight because that allegation is unquestionably false.” D.I. 39 at 11¹. But, while Plaintiffs quibble with the wording of the allegation, Plaintiffs do not dispute the claims were clearly copied, with small modifications. For instance, as set forth below, claim 37 of the ’066 Application is almost completely identical to claim 1 of Guardant U.S. Patent No. 9,834,822 claim 1, with the only differences underlined:

¹ In one counterclaim, Guardant alleges that “Claims 37-39 and 41-43 of the ’066 Application were exact copies of claims 1-3, 6-7, and 10 from Guardant’s ’822 Patent, which issued on December 5, 2017.” D.I. 30 at ¶ 250. Claim 37 and 1 of the ’066 Application and ’822 Patent respectively are near-exact copies with immaterial differences, but Guardant would be willing to amend this allegation to remove the word exact.

Plaintiffs' U.S. Patent Application No. 16/411,066, Claim 37 (5/24/2019)	Guardant's U.S. Patent No. 9,834,822, Claim 1
37. (New) A method, comprising:	1. A method, comprising:
a) providing a population of <u>circulating DNA</u> molecules obtained from a bodily sample from a subject;	a) providing a population of <u>cell free DNA</u> (" <u>cfDNA</u> ") molecules obtained from a bodily sample from a subject;
b) converting the population of <u>circulating DNA</u> molecules into a population of non-uniquely tagged parent polynucleotides, wherein each of the non-uniquely tagged parent polynucleotides comprises (i) a sequence from a <u>circulating DNA</u> molecule of the population of <u>circulating DNA</u> molecules, and (ii) an identifier sequence comprising one or more polynucleotide barcodes, <u>such that each non-uniquely tagged parent polynucleotide is substantially unique with respect to other non-uniquely tagged parent polynucleotides in the population</u> ;	b) converting the population of <u>cfDNA</u> molecules into a population of non-uniquely tagged parent polynucleotides, wherein each of the non-uniquely tagged parent polynucleotides comprises (i) a sequence from a <u>cfDNA</u> molecule of the population of <u>cfDNA</u> molecules, and (ii) an identifier sequence comprising one or more polynucleotide barcodes;
c) amplifying the population of non-uniquely tagged parent polynucleotides to produce a corresponding population of amplified progeny polynucleotides;	c) amplifying the population of non-uniquely tagged parent polynucleotides to produce a corresponding population of amplified progeny polynucleotides;
d) sequencing the population of amplified progeny polynucleotides to produce a set of sequence reads;	d) sequencing the population of amplified progeny polynucleotides to produce a set of sequence reads;
e) mapping sequence reads of the set of sequence reads to <u>a</u> reference sequence;	e) mapping sequence reads of the set of sequence reads to <u>one or more</u> reference sequences <u>from a human genome</u> ;
f) grouping the sequence reads into families, each of the families comprising sequence reads comprising the same identifier sequence and having the same start and stop positions, whereby each of the families comprises sequence reads amplified from the same <u>non-uniquely</u> tagged parent polynucleotide;	f) grouping the sequence reads into families, each of the families comprising sequence reads comprising the same identifier sequence and having the same start and stop positions, whereby each of the families comprises sequence reads amplified from the same tagged parent polynucleotide;
g) at each genetic locus of a plurality of genetic loci in the reference sequence, collapsing sequence reads in each family to	g) at each genetic locus of a plurality of genetic loci in the <u>one or more</u> reference sequences, collapsing sequence reads in each

yield a base call for each family at the genetic locus; and	family to yield a base call for each family at the genetic locus; and
h) determining a frequency of one or more bases called at the locus from among the families.	h) determining a frequency of one or more bases called at the locus from among the families.

The undeniable (and undisputed) similarity of these claims creates the strong inference that the inventors and prosecuting attorney copied Guardant’s claims and belies Plaintiffs’ suggestion that those individuals simply “did not appreciate that the claims were substantially similar.” D.I. 39 at 11. But even if Plaintiffs’ proposed inference is plausible—it is not—Plaintiffs argue the facts, not the sufficiency of Guardant’s allegations taken as true. *York Bldg. Prod. Co.*, 2011 WL 13214367, at *3.

3. Guardant Adequately Pled How Failure To Notify The PTO Of Claim Copying Is Material

Guardant’s counterclaims allege that “applicants’ failure to notify the PTO of the copied claims was material to the patentability . . . because identifying the copied claims would have triggered an interference.” D.I. 30 at ¶¶ 262, 287. Further, the claims “would not have issued if Jesse Salk, Lawrence Loeb, Michael Schmitt, and Lara J. Dueppen had notified the PTO of the copied claims.” *Id.* at ¶¶ 263, 288. These allegations sufficiently plead the materiality of the omissions, namely that but for the omissions, the PTO would have instituted interference proceedings which would have precluded the issuance of each patent. “[T]he plausibility requirement is not akin to a ‘probability requirement at the pleading stage; it simply calls for enough fact[s] to raise a reasonable expectation that discovery will reveal’ that the defendant is liable for the misconduct alleged.” *In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1341 (Fed. Cir. 2012) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

Contrary to Plaintiffs' argument, Guardant's allegations properly address materiality. For example, Guardant's counterclaims allege that "identifying the copied claims would have triggered an interference," and that the "[p]atent[s] would not have issued if Jesse Salk, Lawrence Loeb, Michael Schmitt, and Lara J. Dueppen had notified the PTO of the copied claims." D.I. 30 at ¶¶ 262, 263, 287, 288. Moreover, Guardant has pled, with sufficient detail, that in the one instance where Jesse Salk, Lawrence Loeb, Michael Schmitt, and Lara J. Dueppen disclosed claim copying "no patent issued." *Id.* at ¶¶ 268, 293. Ignoring this, Plaintiffs argue that "Guardant does not plead facts plausibly explaining why an interference would have been triggered or how and why an examiner would have used the undisclosed information to reject UW's claims." D.I. 39 at 14. This ignores the pleading standard and instead implies that Guardant need proofs which are unavailable at this stage.

Plaintiffs' argument that "the '699 and '951 patents, which admittedly claim priority before the effective date of the AIA, would lose in a priority contest to Guardant's post-AIA filings," D.I. 39 at 14, is a complicated question of fact and law inappropriate for resolution on the pleadings. But the issue here is not a "priority contest" based on priority date (which Guardant may challenge in this case), but rather an issue of undisclosed claim copying. "When a claim is copied from another patent for interference purposes, it must be supported by the specification of the copier." *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1332 (Fed. Cir. 2000). Plaintiffs' copied claims may be unsupported by the specifications therefore the priority date of the applications containing the copied claims is not dispositive. *See, e.g.*, D.I. 30 at 19 (Third Affirmative Defense). Similarly, Plaintiffs' argument that "the allegedly copied claims changed before they issued" is also misplaced. D.I. 39 at 14. The fact that the claims changed throughout prosecution does not limit the applicability of Section 135(b). Pre-AIA

Section 135 addresses a claim “made in an application,” not a “claim as issued.” 35 U.S.C. § 135(b)(1).

Further, that the applicants cited the patent in an Information Disclosure Statement (“IDS”) does not dispel them of their duty of candor to disclose their claim copying. “PTO Rule 56, codified at 37 C.F.R. § 1.56, imposes on all individuals associated with the filing and prosecution of a patent application a duty of candor and good faith in dealing with the PTO during the period of examination of a patent application.” *Avid Identification Sys., Inc. v. Crystal Imp. Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010) (citing 37 C.F.R. § 1.56(a)). The duty of candor includes a duty to disclose to the PTO all information known to each individual that is material to the issue of patentability. *Id.*

Because Guardant has adequately alleged each element of inequitable conduct, Plaintiffs’ motion on these counts should be denied.

B. Guardant Has Pled Sufficient Facts To Support Its Unpatentability Counterclaims.

1. The Alleged Facts Are Sufficient To Show That the ’699 and ’951 Patents Fail to Properly Identify The Inventors.

“A patent is invalid if more or less than the true inventors are named.” *Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1301 (Fed. Cir. 2002). Here, Plaintiffs and Guardant agree that to allege improper inventorship, Guardant “must allege facts that show the ’699 and ’951 patents name as inventors more or fewer people than the true inventors.” D.I. 39 at 16.

Guardant has done precisely that, pleading that “TwinStrand has also shamelessly attacked Guardant’s patent portfolio by copying Guardant’s own patent claims into TwinStrand patent applications—misrepresenting TwinStrand employees and founders as the true inventors of the claimed inventions” (D.I. 30 ¶ 124), “[t]he ’699 Patent fails to name the actual inventor of the

claimed subject matter” (*Id.* ¶ 228), and “[t]he ’951 Patent fails to name the actual inventor of the claimed subject matter.” *Id.* ¶ 238.

Guardant need not plead facts regarding conception and reduction to practice by the alleged correct inventors at this stage. Rather, “[a] patent may be invalid simply because it names the wrong inventors” and allegations of statutory invalidity due to improper inventorship need not be accompanied by the names of the supposed correct inventors. *Belcher Pharms., LLC v. Hospira, Inc.*, No. 17-775-LPS, 2019 WL 2503159, at *1 n.1 (D. Del. June 5, 2019) (citing 35 U.S.C. §§ 101, 115, 282). Even if this were the correct standard, Guardant’s allegations are based on improper copying of claims from Guardant patents. Thus the inventors of Guardant’s claimed inventions are the proper inventors here. *See* D.I. 30 at ¶ 142 (“Guardant’s ’822 Patent titled ‘Systems and methods to detect rare mutations and copy number variation’ issued on December 5, 2017 and names AmirAli Talasaz as inventor of the claimed subject matter.”) and *id.* at ¶ 146 (“The named inventors of the subject matter of Guardant’s Patent Application WO2015/100427 are Helmy Eltoukhy and AmirAli Talasaz.”). Guardant has thus adequately alleged unpatentability for improper inventorship, and Plaintiffs’ motion to dismiss these counts should be denied on this basis alone.

2. Pre-AIA Section 135(b) Provides a Cause of Action

Plaintiffs’ motion asks this Court to dismiss Guardant’s counterclaims of unpatentability under Sections 101, 115, and 135. D.I. 30 at ¶ 227, 237. But nowhere do Plaintiffs argue that unpatentability under Sections 101 and 115 are not cognizable causes of action and/or affirmative defenses. Instead, Plaintiffs focus on Section 135 and incorrectly assert that it does not provide a basis for invalidity. As discussed below, Plaintiffs’ argument here is inconsistent with analogous Federal Circuit case law.

Proper inventorship is a necessary requirement for a valid patent. As Guardant pled,

Chapter 2157 of the Manual of Patent Examining Procedure states: “Although the AIA eliminated pre-AIA 35 U.S.C. § 102(f), the patent laws still require naming of the actual inventors of the claimed subject matter . . . In the rare situation where it [is] clear that the application does not name the correct inventorship and the applicant has not filed a request to correct inventorship under 37 C.F.R. § 1.48, Office personnel should reject the claims under 35 U.S.C. § 101 and 35 U.S.C. § 115.”

Id. at ¶ 229. *See also Cubist Pharms., Inc. v. Hospira, Inc.*, 75 F. Supp. 3d 641, 673 (D. Del. 2014), *aff’d*, 805 F.3d 1112 n.14 (Fed. Cir. 2015) (“[P]roper inventorship remains a requirement of patentability through § 101.”); *Applied Materials, Inc. v. Multimetrixs, LLC*, No. 06-07372 MHP, 2008 WL 2892453, at *5 (N.D. Cal. July 22, 2008), *aff’d sub nom. Applied Materials, Inc. v. Multimetrix, LLC*, 404 F. App’x 493 (Fed. Cir. 2010) (“An oath of inventorship is a prerequisite for a patent (see 35 U.S.C. § 115; 37 C.F.R. § 1.63(a)(4)) and examiners are required to reject applications on the basis of improper inventorship (see 35 U.S.C. § 102(f)).”).

Under Section 3(n) of the AIA:

The provisions of sections 102(g), 135, and 291 of title 35, United States Code, as in effect on the day before the effective date set forth in paragraph (1) of this subsection, shall apply to each claim of an application for patent, and any patent issued thereon, for which the amendments made by this section also apply, if such application or patent contains or contained at any time--(A) a claim to an invention having an effective filing date as defined in Section 100(i) of title 35, United States Code, that occurs before the effective date set forth in paragraph (1) of this subsection.

Plaintiffs state that “the ’699 and ’951 patents . . . admittedly claim priority before the effective date of the AIA.” D.I. 39 at 14. Thus, pre-AIA § 135(b) applies to the applications that issued as the ’699 and ’951 patents.²

² Guardant does not concede the priority dates of the ’699 and ’951 patents, which are irrelevant to this analysis.

Plaintiffs rely on a single case from the Eastern District of California for the proposition that “Section 135, by its own terms does not provide a basis for invalidity, nor is it an enumerated invalidity defense under 35 U.S.C. § 282.” D.I. 39 at 18. But while § 135 is not expressly recited in § 282, the Federal Circuit reads § 282 to include defenses not expressly identified, including defenses related to errors by the PTO that are analogous to § 135. *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995). In *Quantum*, the Federal Circuit found that a violation of 35 U.S.C. § 305, which states that the scope of amended or new claim cannot be enlarged in PTO reexamination, “is an invalidity defense in a patent infringement action” despite not being expressly identified in § 282. The Federal Circuit found that “the Patent Act is silent regarding the proper remedy to be employed by a district court in a patent infringement suit when it determines that claims were improperly broadened during reexamination in violation of 35 U.S.C. § 305.” *Id.* at 1583 (“Neither the express words in section 305 nor its legislative history provide any guidance in this situation; they merely recite the prohibition against broadening during reexamination.”). The Federal Circuit found that “[i]f the only penalty for violating section 305 is a remand to the PTO to have the reexamined claims narrowed to be commensurate in scope with what the applicant was only entitled to in the first place, then applicants will have an incentive to attempt to broaden their claims during reexamination, and, if successful, be able to enforce these broadened claims against their competitors” and that “[t]his result essentially renders the prohibition in section 305 meaningless.” *Id.* at 1584. The Federal Circuit concluded that its holding “is not inconsistent with 35 U.S.C. § 282” as “Section 282 does not state that the list of invalidity defenses contained therein are the only ones available; the statute merely says ‘[t]he following shall be defenses.’” *Id.*

As in *Quantum*, Guardant seeks to invalidate these patents where, had the inventors and prosecuting attorney disclosed the claim copying, the claims would have been subject to a derivation proceeding and rejected. While § 282 does not expressly identify § 135 as a defense, the Patent Act does not foreclose it as a proper defense, and dismissing this counterclaim would deprive Guardant the opportunity to challenge the claims here—a challenge Guardant should have been permitted to raise at the PTO had it not been for the inventors’ misconduct. Further, as *Quantum* cautions, without allowing § 135 to be asserted as a defense, applicants prosecuting pre-AIA claims will have an incentive to copy claims one year after the original patent issues and unsuspecting third parties in Guardant’s position will have no recourse.

On the contrary, *Chiron Corp. v. Genentech, Inc.*, 268 F. Supp. 2d 1148, 1171 (E.D. Cal. 2002), cited by Plaintiffs (D.I. 39 at 18), incorrectly interpreted Section 282 as providing a finite list of defenses, noting in a parenthetical that it “list[s] defenses available in a patent infringement suit.” There, the Eastern District of California concluded that “Section 135(b) acts as a statute of limitations by placing a one year time limit on when a patent applicant can copy the claims of another inventor’s patent in order to provoke an interference” and that “[i]t is a procedural bar to interference proceedings, not a substantive basis upon which to declare the claims of a patent invalid.” *Id.* Had the court in *Chiron* applied the holding in *Quantum* (that § 282 is not an exhaustive list of all possible invalidity defenses), it would have likely permitted the § 135 invalidity defense to proceed.

Guardant should be allowed to pursue its § 135 defense, particularly here where the discovery on this defense will largely, if not completely, overlap with discovery to be taken in this case, including on the § 101, § 115, and inequitable conduct claims.

C. Guardant’s Affirmative Defenses Are Adequately Pled.

Plaintiffs muddle the pleading standard and ask the Court to strike Guardant’s Fourth and Twelfth, and Eighth affirmative defenses on the same basis as they ask the Court to dismiss Counts V and VI, and VII and VIII respectively. In doing so, Plaintiffs fail to address the distinct pleading standard for affirmative defenses. “The court has held that an allegation that states that the claims of a patent are invalid for ‘fail[ing] to meet the conditions for patentability within the meaning of the patent laws, Title 35 § 101 et seq., including, but not limited to, §§ 101, 102, 103 and/or 112’—while insufficient as a counterclaim to survive a motion to dismiss—is sufficient as an affirmative defense to survive a motion to strike.” *Senju Pharm.*, 921 F. Supp. at 303 (quoting *Internet Media Corp. v. Hearst Newspapers, LLC*, 10–690-SLR, 2012 WL 3867165, at *1, *3 (D. Del. Sept. 6, 2012)).

Here, Guardant’s Fourth and Twelfth Affirmative Defenses are sufficient to put Plaintiffs on fair notice. D.I. 30 at 19 (Fourth Affirmative Defense, “Inventorship/Derivation . . . One or more claims of the ’631 patent, the ’699 patent, the ’951 patent, and the ’127 patent are invalid for failure to name the correct inventors pursuant to 35 U.S.C. § 116 and/or the claims were derived from the inventions of others.”) and 21 (Twelfth Affirmative Defense, “Failure to Comply With Patentability Requirements of 35 U.S.C. § 135 . . . One or more claims of the ’699 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. § 135.”).³ Because neither claim requires fraud or misleading conduct as an element, neither is subject to the *Twombly/Iqbal* or Rule 9(b) pleading standards. *See Bayer CropScience AG v. Dow AgroSciences LLC*, No. 10-1045-RMB (JS), 2011 WL 6934557, at *3 (D. Del. Dec. 30, 2011) (“Because equitable estoppel has misleading conduct by the patent

³ Section 135(b) is an invalidity defense for the reasons stated in Section IV.B.ii above.

holder as one of its elements, Defendant was required to plead this affirmative defense with particularity under Rule 9(b).”).)

Guardant’s Eighth Affirmative Defense, “Unclean Hands,” meets the heightened pleading requirements of Rule 9(b), particularly when read in view of the related counterclaims. D.I. 30 at 20 (“Plaintiffs’ Complaint is barred by the doctrine of unclean hands as a result of the acts, conduct, and omissions of Plaintiffs or others that are attributable to Plaintiffs before, during, and after prosecution of the Asserted Patent and Plaintiffs’ conduct before filing this action and in filing of this action.”). *See, e.g., Sonos, Inc. v. D&M Holdings Inc.*, No. 14-1330-RGA-MPT, 2016 WL 4249493, at *5 (D. Del. Aug. 10, 2016), report and recommendation adopted, No. 14-1330-RGA, 2016 WL 4581078 (D. Del. Sept. 1, 2016) (“Because an element of unclean hands is based in fraud, the defense must be pled with particularity under FED. R. CIV. P. 9(b).”).

As discussed above, Guardant has met the heightened pleading standard of Rule 9 for Counts VII and VIII. Both Guardant’s counterclaim Counts VII and VIII, and its eighth affirmative defense are based on the Applicants’ affirmative omission of their claim copying before the PTO. Therefore, its eighth affirmative defense should not be stricken. *Genentech, Inc. v. Amgen Inc.*, 17-01407-CFC, D.I. 626 at 13-14 (D. Del. Feb. 11, 2020) (denying motion to strike affirmative defenses of inequitable conduct and unclean hands where the affirmative defenses were based on allegations made in support of counterclaims).

Guardant’s Fourth, Twelfth, and Eighth affirmative defenses should therefore not be stricken.

V. CONCLUSION

Guardant respectfully requests that the Court deny Plaintiffs’ partial motion to dismiss for the foregoing reasons.

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Respectfully submitted,

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